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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,043

Applicant(s)

BJORKLUND, ANDERS

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/30/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed November 30, 2004 (hereinafter referred to as "the response") has been entered. Claim 1 has been amended. Claim 4 has been cancelled.

Accordingly, Claims 1-3, 6, 13, and 14 remain pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 30, 2004 has been entered.

Priority

The conditions for receiving benefit of an earlier filing date have been met. This application claims benefit to provisional application 60/160,553, filed October 20, 1999. Thus, the earliest effective filing date of the instant application is October 20, 1999.

Specification

The objection to the specification is withdrawn in view of the amendment to the specification to claim priority solely to provisional application 60/160,553. The correction of inventorship in the provisional application is noted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-3, 6, 13, and 14 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 3-7 of the Office Action mailed 6/3/04, on pages 2-9 of the Office Action mailed 5/12/03, on pages 2-5 of the Office Action mailed 7/16/02, and for further reasons as discussed herein, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At pages 6-8 of the response, Applicants rely on the MPEP at § 2164.01(c) for stating that 35 U.S.C. 112 is satisfied if "the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated" (Applicants' emphasis). Applicants assert that their specification and the evidence of record demonstrates that the ordinarily skilled artisan could discern an appropriate method of use without undue experimentation. Applicants point to the specification teachings relating to how to transplant CNS neural stem cells and induce migration. Applicants further assert that the graft survival and reinnervation shown in the specification are indicative of a therapeutic effect. However, the art cited in this case, particularly Milward et al. demonstrate that even when grafted cells integrate normally, the clinical deficit of the animals is not ameliorated. Given the unpredictability in the art of therapeutic transplantation, the development of therapeutic protocols requires substantial experimentation. In view of the limited guidance, this substantial experimentation rises to the level of undue experimentation.

At pages 8-9 of the response, Applicants assert that the claims do not recite a therapeutic effect. However, the only use contemplated in the specification for the method of transplantation is to produce a therapeutic effect in the subject. Applicants further assert that the specification provides the necessary teachings for performing the transplantation and inducing migration by infusion of growth factor at a second locus. However, guidance for performing the transplantation is not sufficient to enable the instant invention because the specification does not assert a utility for non-therapeutic transplantation. On the contrary, the only utility asserted in the specification for the transplant method is to produce a therapeutic effect.

At pages 9-10 of the response, Applicants assert that the specification describes the procedures for transplanting neural stem cells in Examples 8, 9, and 15 and that the working examples demonstrate the responsiveness of the transplanted cells to an EGF infusion in Examples 9 and 15. Applicants assert that the working examples correlate with the steps recited in the claimed methods, such that the specification is commensurate in scope with the claims. Applicants conclude that this is all that is required to meet the "how to use" portion of the enablement requirement. Applicants further contend that the working examples demonstrate how to use the claimed invention. However, as noted herein above, the specification does not teach a utility for transplanting neural stem cells and inducing their migration to a second site in the absence of a therapeutic effect. The specification only teaches that transplantation should be done in a manner that results in a therapeutic effect. Thus, the function of the transplanted cells must be sufficient to achieve a therapeutic effect, without undue experimentation. For the reasons discussed above, given the state of the art at the time of the invention, undue experimentation would be required to achieve a therapeutic benefit.

At pages 10-13 of the response, Applicants point to a publication of Ishibashi et al. (2004) for demonstrating that the transplantation of neural stem cells into lesioned Mongolian gerbil brains "induced significant improvement in the sensorimotor and cognitive functions of the gerbils after focal ischemia."

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However, this reference does not demonstrate implementation of the claimed invention because it does not involve infusion of a growth factor at a second locus to induce migration to the site. Furthermore, the reference is post-filing art and therefore the skilled artisan would not have had the benefit of the teachings of this reference at the time of the invention. Applicants further point to Ogawa et al. (2002) for teaching that neural progenitor cells transplanted into a rat spinal cord injury model resulted in both neurogenesis and functional recovery. Again, this reference does not demonstrate implementation of the claimed invention because it does not involve infusion of a growth factor at a second locus to induce migration to the site. Furthermore, the reference is post-filing art and therefore the skilled artisan would not have had the benefit of the teachings of this reference at the time of the invention.

Given the lack of applicable working examples directed to therapeutic transplantation, the limited guidance provided in the specification, the broad scope of the claims with regard to the regions of the brain to be treated, and the unpredictability for achieving a therapeutic effect upon the transplantation of neural stem cells, undue experimentation would have been required for one skilled in the art to practice the claimed method of the invention to achieve a therapeutic effect, the only real world utility asserted in the specification.

Thus, the rejection under 35 U.S.C. 112, first paragraph, is maintained.

Conclusion

No claims are allowed.

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All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history

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information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER